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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3762

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/046,137	Applicant(s) TU ET AL.	
	Examiner Patricia M Bianco	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) 1-29 and 48-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-47 and 83-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2&7&11/02;5/03;403</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> . |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 30-47 & 83-85, in the reply filed on 6/30/04 is acknowledged.

Claims 1-29 & 48-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/30/04.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains legal phraseology, namely "adapted". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 30, 31 & 83-85 are rejected under 35 U.S.C. 102(e) as being anticipated by Hill (6,533,768 B1). Hill discloses a surgical method for implanting a trabecular shunt such that the shunt is placed within the trabecular meshwork between the anterior chamber and Schlemm's canal. Hill also discloses that the shunt may have a therapeutic drug integrated in its body. Therefore, when the shunt is in place within the eye it is inherent that a quantity of the drug will be released into the eye. With respect to claims 84 & 85, the recitation that the drug is "adapted to" perform a specific function or result has not been considered since it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires

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the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 44, 46, & 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('768). Hill discloses the invention substantially as claimed, see rejection *supra*, however, fails to disclose specifically that the drug is chosen from those claimed in claims 44, 46 & 47. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose any of a sustained release water soluble medicament, a non-steroidal glucocorticoid antagonist or a prostaglandin analog to be

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the drug incorporated into the shunt, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 34 & 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('768) in view of Wong et al. (5,443,505). Hill discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the drug is a nucleotide analog or TGF-beta. Wong et al. discloses the use of ocular implants for implantation having an incorporated drug, two examples given are nucleotide analog or TGF-beta. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose either nucleotide analog or TGF-beta to be incorporated into the shunt of Hill as taught by Wong, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('768) in view of Miki (5,547,993). Hill discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the drug is 2-(4-methylaminobutoxy) diphenylmethane. Miki discloses the use of is 2-(4-methylaminobutoxy) diphenylmethane for treatment of glaucoma. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

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choose is 2-(4-methylaminobutoxy) diphenylmethane to be incorporated into the shunt of Hill as taught by Miki, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 39 & 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('768) in view of Krauss (5,652,236). Hill discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the drug is N-methylhydroxylamine, butylated hydroxyanisole, or methylene blue. Krauss discloses the use of N-methylhydroxylamine, butylated hydroxyanisole, or methylene blue for use in treating glaucoma. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose N-methylhydroxylamine, butylated hydroxyanisole, or methylene blue to be incorporated into the shunt of Hill as taught by Krauss, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('768) in view of DeSantis (5,502,052). Hill discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the drug a combination of apraclonidine and timolol. DeSantis discloses the use of a combination of apraclonidine and timolol for treatment of glaucoma. It would have been obvious to one having ordinary skill in the art at the time the invention was made to a combination

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of apraclonidine and timolol to be incorporated into the shunt of Hill as taught by DeSantis, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('768) in view of Adorante et al. (5,925,342). Hill discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the drug is potassium channel blockers. Adorante discloses the use of potassium channel blockers for treatment of glaucoma. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have potassium channel blockers incorporated into the shunt of Hill as taught by Adorante, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('768) in view of Ogawa et al. (EP 0 955 045 A1). Hill discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the drug is 5-[1-hydroxy-2-[2-(2-methoxyphenoxy)ethylamino]ethyl]-2-methylbenzenesulfonamide. Ogawa discloses the use of 5-[1-hydroxy-2-[2-(2-methoxyphenoxy)ethylamino]ethyl]-2-methylbenzenesulfonamide for treatment of ocular disorders. It would have been obvious to one having ordinary skill in the art at

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the time the invention was made to have 5-[1-hydroxy-2-[2-(2-methoxyphenoxy)ethylamino]ethyl]-2-methylbenzenesulfonamide incorporated into the shunt of Hill as taught by Ogawa, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('768) in view of Schwartz et al. (6,054,485). Hill discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the drug is a synthetic oligonucleotide. Schwartz discloses the use of a synthetic oligonucleotide for use in treating the eye. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose a synthetic oligonucleotide to be incorporated into the shunt of Hill as taught by Schwartz, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('768) in view of Wang et al. (6,201,001). Hill discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the drug is Imidazole antiproliferative agents. Wang discloses the use of a Imidazole antiproliferative agents for use in methods where cell proliferation is undesired. It would

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have been obvious to one having ordinary skill in the art at the time the invention was made to choose Imidazole antiproliferative agents to be incorporated into the shunt of Hill as taught by Wang, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('768) in view of Wheeler et al. (6,194,415). Hill discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the drug is quinoxalines. Wheeler discloses the use of quinoxalines for use in methods treating the eye. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose quinoxalines to be incorporated into the shunt of Hill as taught by Wheeler, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('768) in view of Klimko et al. (6,184,250). Hill discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the drug is cloprostenol or fluporstenol analogs. Klimko discloses the use of cloprostenol or fluporstenol analogs for use in glaucoma treatment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose cloprostenol

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or fluporstenol analogs to be incorporated into the shunt of Hill as taught by Klimko, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('768) in view of Kaufman et al. (6,110,91250). Hill discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the drug is a serine-threonine kinase inhibitor. Kaufman discloses the use of serine-threonine kinase inhibitor for use in glaucoma treatment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose serine-threonine kinase inhibitor to be incorporated into the shunt of Hill as taught by Kaufman, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 23rd, 2004


PATRICIA BIANCO
PRIMARY EXAMINER

Patricia M Bianco
Primary Examiner
Art Unit 3762